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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,472	01/28/2002	Eric F. Bernstein	BERN-0045	2557

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,472

Applicant(s)

Bernstein, E. F.

Examiner

Scott D. Priebe, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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DETAILED ACTION

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. The cover sheet of the PCT publication does not meet this requirement.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a reporter gene operably linked to the human elastin

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promoter. The claims recite "capable of expressing human elastin promoter." This phrase does not make sense due to the known function of promoters, i.e. promoters mediate gene expression, they are not expressed *per se*. The specification (page 6, lines 7-10) discloses that expression from the human elastin promoter is measured by measuring expression of a reporter gene, such as CAT.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

(f) he did not himself invent the subject matter sought to be patented.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bernstein et al., US 5,648,061, as evidenced by applicant's admission of prior art in the specification.

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Bernstein et al. discloses a system and method for identifying agents clearly readable on the instant claims. The system comprises fibroblasts obtained from a transgenic mouse whose genome contains a reporter gene construct comprising a human elastic promoter operable linked to a CAT structural gene, and a UVB light source. The disclosed method involves treating the fibroblasts with UVB radiation in the presence and absence of a test compound and comparing expression from the elastin promoter, as measured by the level of reporter gene expression, in response to UVB radiation. Lower expression in the presence of the test compound than in its absence indicates that the compound inhibits or prevents UVB damage. See entire document, especially col. 4, line 64, to col. 5, line 6, and claim 2.

As indicated in the instant specification, it was well known that UV irradiation of cells causes formation of reactive oxygen species. Thus, even though Bernstein does not disclose this characteristic of UV irradiation, the characteristic is inherent, and disclosure of UV irradiation and the means therefor meets the limitation of the claims for "means for generating reactive oxygen species."

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Bernstein et al., US 6,018,098 as evidenced by applicant's admission of prior art in the specification.

Bernstein et al. discloses a system and method for identifying agents clearly readable on the instant claims. The system comprises fibroblasts obtained from a transgenic mouse whose

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genome contains a reporter gene construct comprising a human elastic promoter operable linked to a CAT structural gene, and a UVB light source or a UVA light source combined with 8-methoxypsoralen. The disclosed method involves treating the fibroblasts with either UVB radiation or with a combination of UVA radiation and 8-MOP in the presence and absence of a test compound and comparing expression from the elastin promoter, as measured by the level of reporter gene expression, in response to either UVB radiation or a combination of UVA radiation and 8-MOP. Lower expression in the presence of the test compound than in its absence indicates that the compound inhibits or prevents UVB or UVA damage. See especially col. 1, lines 48-52; col. 4, lines 25-65; col. 5, lines 26-37; and claim 2.

As indicated in the specification, it was well known that UV irradiation of cells causes formation of reactive oxygen species. Thus, even though Bernstein does not disclose this characteristic of UV irradiation, the characteristic is inherent, and disclosure of UV irradiation and the means therefor meets the limitation of the claims for "means for generating reactive oxygen species."

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

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Claims 1-2 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Bernstein and Uitto jointly invented the subject matter claimed in the '061 and '098 patents described above, as claimed in claim 2 of each patent. This patented subject matter is embraced by the instant claims.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bernstein et al., WO 96/37237, as evidenced by applicant's admission of prior art in the specification.

Bernstein et al. discloses a system and method for identifying agents clearly readable on the instant claims. The system comprises fibroblasts obtained from a transgenic mouse whose genome contains a reporter gene construct comprising a human elastic promoter operable linked to a CAT structural gene, and a UVB light source or a UVA light source combined with 8-methoxypsoralen. The disclosed method involves treating the fibroblasts with either UVB radiation or with a combination of UVA radiation and 8-MOP in the presence and absence of a test compound and comparing expression from the elastin promoter, as measured by the level of reporter gene expression, in response to either UVB radiation or a combination of UVA radiation and 8-MOP. Lower expression in the presence of the test compound than in its absence indicates that the compound inhibits or prevents UVB or UVA damage. See especially page 2, lines 27-29; page 7, line 1 to page 8, line 3; page 8, line 29 to page 9, line 2; and claim 4.

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As indicated in the specification, it was well known that UV irradiation of cells causes formation of reactive oxygen species. Thus, even though Bernstein does not disclose this characteristic of UV irradiation, the characteristic is inherent, and disclosure of UV irradiation and the means therefor meets the limitation of the claims for "means for generating reactive oxygen species."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of each of U.S. Patent Nos. 5,648,061 and 6,018,098. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 2 embraces the methods of claim 2 of each patent, and instant claim 1 embraces the systems disclosed by claim 2 of each patent.

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It is unclear whether the instant application is commonly assigned with either of U.S. Patent Nos. 5,648,061 and 6,018,098 described above. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). If either or both patents are commonly assigned, they would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made.

If the instant application is commonly assigned with either or both of the '061 and '098 patents, then in order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

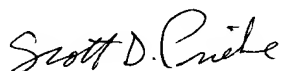
A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

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Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



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